



Clinical trial results: Medically Ill Patient Assessment of Rivaroxaban Versus Placebo in Reducing Post-Discharge Venous Thrombo-Embolism Risk Summary

| | |
|--------------------------|---|
| EudraCT number | 2014-000305-13 |
| Trial protocol | DK HU CZ IT ES NL LT BG GR LV AT DE GB PT SK HR |
| Global end of trial date | 03 May 2018 |

Results information

| | |
|--------------------------------|--------------|
| Result version number | v1 (current) |
| This version publication date | 05 May 2019 |
| First version publication date | 05 May 2019 |

Trial information

Trial identification

| | |
|-----------------------|----------------|
| Sponsor protocol code | RIVAROXDVT3002 |
|-----------------------|----------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02111564 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Janssen Research & Development LLC |
| Sponsor organisation address | 920 US Highway 202, Raritan, United States, NJ 08869 |
| Public contact | Clinical Registry group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com |
| Scientific contact | Clinical Registry group, Janssen Research & Development LLC, ClinicalTrialsEU@its.jnj.com |

Notes:

Paediatric regulatory details

| | |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

Results analysis stage

| | |
|--|-------------|
| Analysis stage | Final |
| Date of interim/final analysis | 03 May 2018 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 03 May 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to assess the efficacy and safety of rivaroxaban, compared with placebo in the prevention of symptomatic venous thromboembolism events (lower extremity deep vein thrombosis [DVT] and non-fatal pulmonary embolism [PE]) and venous thromboembolism events-related death (death due to PE or death in which PE could not be ruled out as the cause) post hospital discharge in high-risk, medically ill subjects.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices (GCP) and applicable regulatory requirements. Safety assessments included adverse event and International Society on Thrombosis and Haemostasis (ISTH) major bleeding, non-major clinically relevant bleeding, other bleeding and clinical laboratory tests.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 10 June 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-----------------------------|
| Country: Number of subjects enrolled | Argentina: 242 |
| Country: Number of subjects enrolled | Australia: 88 |
| Country: Number of subjects enrolled | Austria: 14 |
| Country: Number of subjects enrolled | Bulgaria: 1428 |
| Country: Number of subjects enrolled | Bosnia and Herzegovina: 597 |
| Country: Number of subjects enrolled | Belarus: 133 |
| Country: Number of subjects enrolled | Brazil: 92 |
| Country: Number of subjects enrolled | Canada: 43 |
| Country: Number of subjects enrolled | Colombia: 140 |
| Country: Number of subjects enrolled | Czech Republic: 231 |
| Country: Number of subjects enrolled | Germany: 17 |
| Country: Number of subjects enrolled | Denmark: 7 |
| Country: Number of subjects enrolled | Spain: 383 |
| Country: Number of subjects enrolled | Estonia: 11 |
| Country: Number of subjects enrolled | United Kingdom: 8 |
| Country: Number of subjects enrolled | Georgia: 1762 |
| Country: Number of subjects enrolled | Greece: 131 |

| | |
|--------------------------------------|---|
| Country: Number of subjects enrolled | Croatia: 270 |
| Country: Number of subjects enrolled | Hungary: 549 |
| Country: Number of subjects enrolled | Israel: 111 |
| Country: Number of subjects enrolled | Italy: 147 |
| Country: Number of subjects enrolled | Lithuania: 164 |
| Country: Number of subjects enrolled | Latvia: 308 |
| Country: Number of subjects enrolled | Mexico: 32 |
| Country: Number of subjects enrolled | Macedonia, the former Yugoslav Republic of: 902 |
| Country: Number of subjects enrolled | Netherlands: 17 |
| Country: Number of subjects enrolled | Peru: 65 |
| Country: Number of subjects enrolled | Poland: 619 |
| Country: Number of subjects enrolled | Puerto Rico: 1 |
| Country: Number of subjects enrolled | Portugal: 13 |
| Country: Number of subjects enrolled | Romania: 324 |
| Country: Number of subjects enrolled | Russian Federation: 1142 |
| Country: Number of subjects enrolled | Serbia: 609 |
| Country: Number of subjects enrolled | Turkey: 70 |
| Country: Number of subjects enrolled | Ukraine: 854 |
| Country: Number of subjects enrolled | United States: 290 |
| Country: Number of subjects enrolled | South Africa: 205 |
| Worldwide total number of subjects | 12019 |
| EEA total number of subjects | 4641 |

Notes:

Subjects enrolled per age group

| | |
|---|------|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 3655 |
| From 65 to 84 years | 7626 |
| 85 years and over | 738 |

Subject disposition

Recruitment

Recruitment details:

This study was conducted from 10-June-2014 to 03-May-2018.

Pre-assignment

Screening details:

13708 subjects were screened for eligibility. Of these 12024 subjects were randomized (Rivaroxaban- 6007 and Placebo- 6017). 5 subjects in placebo were excluded from ITT population (2-invalid consent, 3 randomized prior to Health Authority approval).

Period 1

| | |
|------------------------------|--------------------------------|
| Period 1 title | Overall Study (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|-----------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Rivaroxaban 10 mg or 7.5 mg |

Arm description:

Subjects with a creatinine clearance (CrCl) at screening greater than or equal to (\geq) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days.

| | |
|--|---------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | Rivaroxaban |
| Investigational medicinal product code | |
| Other name | JNJ-39039039, BAY 59-7939 |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects were randomised to receive 10 mg or 7.5 mg rivaroxaban tablet once daily for 45 days.

| | |
|------------------|---------|
| Arm title | Placebo |
|------------------|---------|

Arm description:

Subjects received matching placebo tablet once daily for 45 days.

| | |
|--|--------------------|
| Arm type | Placebo comparator |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Subjects received matching placebo tablet once daily for 45 days.

| Number of subjects in period 1 | Rivaroxaban 10 mg or 7.5 mg | Placebo |
|---------------------------------------|--|----------------|
| Started | 6007 | 6012 |
| Safety | 5982 | 5980 |
| Completed | 5876 | 5869 |
| Not completed | 131 | 143 |
| Adverse event, serious fatal | 92 | 99 |
| Consent withdrawn by subject | 20 | 20 |
| Adverse event, non serious | 11 | 13 |
| Adverse event, serious non-fatal | 6 | 8 |
| Lost to follow-up | 2 | 3 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|-----------------------------|
| Reporting group title | Rivaroxaban 10 mg or 7.5 mg |
|-----------------------|-----------------------------|

Reporting group description:

Subjects with a creatinine clearance (CrCl) at screening greater than or equal to (\geq) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days.

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Subjects received matching placebo tablet once daily for 45 days.

| Reporting group values | Rivaroxaban 10 mg or 7.5 mg | Placebo | Total |
|---|-----------------------------|-------------|-------|
| Number of subjects | 6007 | 6012 | 12019 |
| Title for AgeCategorical Units: subjects | | | |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 1809 | 1846 | 3655 |
| From 65 to 84 years | 3866 | 3760 | 7626 |
| 85 years and over | 332 | 406 | 738 |
| Title for AgeContinuous Units: years | | | |
| arithmetic mean | 69.7 | 69.7 | |
| standard deviation | ± 10.6 | ± 10.22 | - |
| Title for Gender Units: subjects | | | |
| Male | 3130 | 3154 | 6284 |
| Female | 2877 | 2858 | 5735 |

End points

End points reporting groups

| | |
|---|-----------------------------|
| Reporting group title | Rivaroxaban 10 mg or 7.5 mg |
| Reporting group description: Subjects with a creatinine clearance (CrCl) at screening greater than or equal to (\geq) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days. | |
| Reporting group title | Placebo |
| Reporting group description: Subjects received matching placebo tablet once daily for 45 days. | |

Primary: Event Rate Based on the Time to the First Occurrence of Composite of all Symptomatic Venous Thromboembolism (VTE) and VTE-Related Death Adjudicated by Clinical Event Committee (CEC)

| | |
|--|---|
| End point title | Event Rate Based on the Time to the First Occurrence of Composite of all Symptomatic Venous Thromboembolism (VTE) and VTE-Related Death Adjudicated by Clinical Event Committee (CEC) |
| End point description: Symptomatic VTE included lower extremity deep vein thrombosis (DVT) and non-fatal pulmonary embolism (PE). Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. Intention-to-treat (ITT) analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received. | |
| End point type | Primary |
| End point timeframe: Up to Day 45 | |

| End point values | Rivaroxaban 10 mg or 7.5 mg | Placebo | | |
|---|-----------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6007 | 6012 | | |
| Units: Events per 100 patients in 45 days | | | | |
| number (not applicable) | 0.84 | 1.11 | | |

Statistical analyses

| | |
|----------------------------|---------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Rivaroxaban 10 mg or 7.5 mg v Placebo |

| | |
|---|--------------------------------|
| Number of subjects included in analysis | 12019 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.136 |
| Method | Cox proportional hazards model |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.76 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.52 |
| upper limit | 1.09 |

Primary: Event Rate based on Time from Randomization to the First occurrence of Major Bleeding Adjudicated by CEC

| | |
|-----------------|--|
| End point title | Event Rate based on Time from Randomization to the First occurrence of Major Bleeding Adjudicated by CEC |
|-----------------|--|

End point description:

A major bleeding event was defined using validated International Society on Thrombosis and Haemostasis (ISTH) bleeding criteria. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or last dose + 2 days. The Safety analysis set included all enrolled subjects in the ITT analysis set who received at least 1 dose of study drug.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 45 Days

| End point values | Rivaroxaban 10 mg or 7.5 mg | Placebo | | |
|---|-----------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 5982 | 5980 | | |
| Units: Events per 100 patients in 45 days | | | | |
| number (not applicable) | 0.28 | 0.15 | | |

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Rivaroxaban 10 mg or 7.5 mg v Placebo |
| Number of subjects included in analysis | 11962 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.124 |
| Method | Cox proportional hazards model |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 1.88 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.84 |
| upper limit | 4.23 |

Secondary: Event Rate Based on Time from Randomization to an Occurrence of VTE-Related Death Adjudicated by CEC

| | |
|-----------------|--|
| End point title | Event Rate Based on Time from Randomization to an Occurrence of VTE-Related Death Adjudicated by CEC |
|-----------------|--|

End point description:

Time from randomization to an occurrence of VTE-related death was assessed. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 45

| End point values | Rivaroxaban 10 mg or 7.5 mg | Placebo | | |
|---|-----------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6007 | 6012 | | |
| Units: Events per 100 patients in 45 days | | | | |
| number (not applicable) | 0.72 | 0.77 | | |

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Rivaroxaban 10 mg or 7.5 mg v Placebo |
| Number of subjects included in analysis | 12019 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.751 |
| Method | Cox proportional hazards model |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.93 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.62 |
| upper limit | 1.42 |

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Symptomatic Venous Thromboembolism Event (VTE) Adjudicated by CEC

| | |
|-----------------|--|
| End point title | Event Rate Based on Time from Randomization to the First Occurrence of a Symptomatic Venous Thromboembolism Event (VTE) Adjudicated by CEC |
|-----------------|--|

End point description:

Time from randomization to the first occurrence of a symptomatic VTE was assessed. Symptomatic VTE included lower extremity DVT and non-fatal PE. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 45

| | | | | |
|---|-----------------------------|-----------------|--|--|
| End point values | Rivaroxaban 10 mg or 7.5 mg | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6007 | 6012 | | |
| Units: Events per 100 patients in 45 days | | | | |
| number (not applicable) | 0.19 | 0.42 | | |

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Rivaroxaban 10 mg or 7.5 mg v Placebo |
| Number of subjects included in analysis | 12019 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.023 |
| Method | Cox proportional hazards model |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.44 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.22 |
| upper limit | 0.89 |

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE and All-Cause Mortality (ACM) Adjudicated by CEC

| | |
|-----------------|--|
| End point title | Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE and All-Cause Mortality (ACM) Adjudicated by CEC |
|-----------------|--|

End point description:

Time from randomization to the first occurrence of a composite of symptomatic VTE and ACM was assessed. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to Day 45

| End point values | Rivaroxaban 10 mg or 7.5 mg | Placebo | | |
|---|-----------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6007 | 6012 | | |
| Units: Events per 100 patients in 45 days | | | | |
| number (not applicable) | 1.31 | 1.80 | | |

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Rivaroxaban 10 mg or 7.5 mg v Placebo |
| Number of subjects included in analysis | 12019 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.033 |
| Method | Cox proportional hazards model |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.73 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.54 |
| upper limit | 0.97 |

Secondary: Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE, Myocardial Infarction (MI), Non-Hemorrhagic Stroke, and Cardiovascular (CV) Death Adjudicated by CEC

| | |
|-----------------|---|
| End point title | Event Rate Based on Time from Randomization to the First Occurrence of a Composite of Symptomatic VTE, Myocardial Infarction (MI), Non-Hemorrhagic Stroke, and Cardiovascular (CV) Death Adjudicated by CEC |
|-----------------|---|

End point description:

Time from randomization to the first occurrence of a composite of symptomatic VTE (lower extremity DVT and non-fatal PE), MI, non-hemorrhagic stroke, and CV death (death due to a known CV cause and death in which a CV cause cannot be ruled out; by this definition, a VTE-related death was considered a CV death) was reported. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or

Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to Day 45 | |

| End point values | Rivaroxaban 10 mg or 7.5 mg | Placebo | | |
|---|-----------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6007 | 6012 | | |
| Units: Events per 100 patients in 45 days | | | | |
| number (not applicable) | 1.58 | 2.03 | | |

Statistical analyses

| | |
|---|---------------------------------------|
| Statistical analysis title | Statistical Analysis 1 |
| Comparison groups | Rivaroxaban 10 mg or 7.5 mg v Placebo |
| Number of subjects included in analysis | 12019 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.073 |
| Method | Cox proportional hazards model |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.78 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.6 |
| upper limit | 1.02 |

Secondary: Event Rate Based on Time from Randomization to an Occurrence of ACM Adjudicated by CEC

| | |
|--|--|
| End point title | Event Rate Based on Time from Randomization to an Occurrence of ACM Adjudicated by CEC |
| End point description: | |
| Time from randomization to an occurrence of all-cause mortality (ACM) was assessed. Event rate is defined as number of events per 100 subjects in 45 days of follow up. Subjects who did not have events are censored on the minimum of last visit before or on death, or Day 45. ITT analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to Day 45 | |

| End point values | Rivaroxaban 10 mg or 7.5 mg | Placebo | | |
|---|-----------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 6007 | 6012 | | |
| Units: Events per 100 patients in 45 days | | | | |
| number (not applicable) | 1.19 | 1.49 | | |

Statistical analyses

| Statistical analysis title | Statistical Analysis 1 |
|---|---------------------------------------|
| Comparison groups | Rivaroxaban 10 mg or 7.5 mg v Placebo |
| Number of subjects included in analysis | 12019 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.156 |
| Method | Cox proportional hazards model |
| Parameter estimate | Hazard ratio (HR) |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.58 |
| upper limit | 1.09 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Approximately 80 days

Adverse event reporting additional description:

Intention-to-treat (ITT) analysis set comprised all randomized subjects who signed a valid informed consent, regardless of actual treatment received.

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 20.1 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-----------------------------|
| Reporting group title | Rivaroxaban 10 mg or 7.5 mg |
|-----------------------|-----------------------------|

Reporting group description:

Subjects with a creatinine clearance (CrCl) at screening greater than or equal to (\geq) 50 milliliter per minute (mL/min) at screening received 10 milligram (mg) rivaroxaban tablet once daily orally and subjects with a creatinine clearance at screening from ≥ 30 to less than ($<$) 50 mL/min at screening received 7.5 mg rivaroxaban tablet once daily for 45 days.

| | |
|-----------------------|---------|
| Reporting group title | Placebo |
|-----------------------|---------|

Reporting group description:

Subjects received matching placebo tablet once daily for 45 days.

| Serious adverse events | Rivaroxaban 10 mg or 7.5 mg | Placebo | |
|---|-----------------------------|--------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 475 / 6007 (7.91%) | 493 / 6012 (8.20%) | |
| number of deaths (all causes) | 115 | 126 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Acute Leukaemia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenocarcinoma | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Adenocarcinoma of Colon | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder Cancer Recurrent | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder Neoplasm | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Cancer | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Neoplasm | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colon Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Gastric Cancer | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hepatic Cancer Metastatic | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Invasive Ductal Breast Carcinoma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Cancer Metastatic | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Lung Infiltration Malignant | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Neoplasm | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lung Neoplasm Malignant | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 5 / 6012 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Malignant Neoplasm of Unknown Primary Site | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Malignant Pleural Effusion | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinum Neoplasm | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningioma | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metastatic Neoplasm | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Non-Hodgkin's Lymphoma | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Non-Small Cell Lung Cancer | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian Cancer | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Plasma Cell Myeloma | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal Cancer | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal Neoplasm | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectosigmoid Cancer | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Neoplasm | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Squamous Cell Carcinoma of Lung | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Aortic Dissection | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic Stenosis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arterial Stenosis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Distributive Shock | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive Crisis | | | |

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|--|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension | | | |
| subjects affected / exposed | 5 / 6007 (0.08%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Peripheral Arterial Occlusive Disease | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Artery Occlusion | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Artery Thrombosis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Ischaemia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post Thrombotic Syndrome | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Hospitalisation | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |

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|---|-------------------|-------------------|--|
| Asthenia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest Pain | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |
| subjects affected / exposed | 25 / 6007 (0.42%) | 30 / 6012 (0.50%) | |
| occurrences causally related to treatment / all | 1 / 25 | 0 / 30 | |
| deaths causally related to treatment / all | 1 / 25 | 0 / 30 | |
| Fatigue | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Multiple Organ Dysfunction Syndrome | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Oedema Peripheral | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripheral Swelling | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden Cardiac Death | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 2 | |
| Systemic Inflammatory Response Syndrome | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic Reaction | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Bereavement | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immobile | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute Pulmonary Oedema | | | |
| subjects affected / exposed | 4 / 6007 (0.07%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Acute Respiratory Failure | | | |
| subjects affected / exposed | 7 / 6007 (0.12%) | 9 / 6012 (0.15%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Asthma | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 8 / 6007 (0.13%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiectasis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Bronchitis Chronic | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Obstructive Pulmonary Disease | | | |
| subjects affected / exposed | 81 / 6007 (1.35%) | 77 / 6012 (1.28%) | |
| occurrences causally related to treatment / all | 0 / 88 | 0 / 87 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 3 | |
| Chronic Respiratory Failure | | | |
| subjects affected / exposed | 4 / 6007 (0.07%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 5 / 6012 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrothorax | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Interstitial Lung Disease | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lupus Pleurisy | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pickwickian Syndrome | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pleural Effusion | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia Aspiration | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax Spontaneous | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Arterial Hypertension | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Congestion | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Fibrosis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Mass | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Oedema | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 4 / 6012 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pulmonary Pneumatocele | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory Distress | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory Failure | | | |
| subjects affected / exposed | 9 / 6007 (0.15%) | 8 / 6012 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 5 | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conversion Disorder | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Panic Attack | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Product issues | | | |
| Device Dislocation | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device Failure | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Device Occlusion | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Aspiration Bronchial | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Body Temperature Increased | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac Output Decreased | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial Necrosis Marker | | | |

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|---|------------------|------------------|--|
| Increased | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Accidental Overdose | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical Vertebral Fracture | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femoral Neck Fracture | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Femur Fracture | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head Injury | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip Fracture | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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| Humerus Fracture | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal Anastomosis Complication | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Laceration | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament Rupture | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower Limb Fracture | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple Injuries | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Nerve Injury | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural Pneumothorax | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rib Fracture | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft Tissue Injury | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon Injury | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity to Various Agents | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic Lung Injury | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Twiddler's Syndrome | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Acute Left Ventricular Failure | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Angina Pectoris | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 3 / 6007 (0.05%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aortic Valve Incompetence | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 13 / 6007 (0.22%) | 10 / 6012 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial Flutter | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 6 / 6012 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular Block Complete | | | |
| subjects affected / exposed | 4 / 6007 (0.07%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrioventricular Block Second Degree | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradyarrhythmia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bradycardia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac Arrest | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 5 / 6007 (0.08%) | 5 / 6012 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 4 | |
| Cardiac Asthma | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac Failure | | | |
| subjects affected / exposed | 51 / 6007 (0.85%) | 62 / 6012 (1.03%) | |
| occurrences causally related to treatment / all | 0 / 53 | 0 / 69 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 8 | |
| Cardiac Failure Acute | | | |
| subjects affected / exposed | 14 / 6007 (0.23%) | 14 / 6012 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 1 | |
| Cardiac Failure Chronic | | | |
| subjects affected / exposed | 13 / 6007 (0.22%) | 8 / 6012 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 1 | |
| Cardiac Failure Congestive | | | |
| subjects affected / exposed | 24 / 6007 (0.40%) | 25 / 6012 (0.42%) | |
| occurrences causally related to treatment / all | 0 / 27 | 0 / 26 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 5 | |
| Cardiac Valve Disease | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac Ventricular Thrombosis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-Respiratory Arrest | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 5 / 6007 (0.08%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 2 | |
| Cardiogenic Shock | | | |
| subjects affected / exposed | 4 / 6007 (0.07%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Cardiomyopathy | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Cardiomyopathy Acute | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Cardiopulmonary Failure | | | |
| subjects affected / exposed | 4 / 6007 (0.07%) | 4 / 6012 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 4 | 0 / 4 | |
| Congestive Cardiomyopathy | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cor Pulmonale | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary Artery Disease | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coronary Artery Stenosis | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diastolic Dysfunction | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive Heart Disease | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Interventricular Septum Rupture | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic Cardiomyopathy | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Left Ventricular Failure | | | |
| subjects affected / exposed | 4 / 6007 (0.07%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Mitral Valve Incompetence | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial Fibrosis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial Ischaemia | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 1 | |
| Myocarditis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Nodal Rhythm | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pericarditis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Right Ventricular Failure | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus Bradycardia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinus Node Dysfunction | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Supraventricular Tachycardia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tachycardia | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular Extrasystoles | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ventricular Tachycardia | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Nervous system disorders | | | |
| Aphasia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Carotid Artery Occlusion | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid Artery Stenosis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Craniocervical Syndrome | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Demyelinating Polyneuropathy | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalopathy | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial Paralysis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemic Coma | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Hypoglycaemic Encephalopathy | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ischaemic Stroke | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar Radiculopathy | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orthostatic Intolerance | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Presyncope | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 6 / 6007 (0.10%) | 5 / 6012 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular Encephalopathy | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral Artery Stenosis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo CNS Origin | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 6007 (0.05%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Autoimmune Haemolytic Anaemia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic Anaemia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Motion Sickness | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo Positional | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |

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|---|------------------|------------------|--|
| Conjunctival Oedema | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exophthalmos | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal Artery Occlusion | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal Incarcerated Hernia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal Pain | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Abdomen | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Gastritis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis Ischaemic | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Duodenal Ulcer | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysphagia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis Haemorrhagic | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterovesical Fistula | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric Polyps | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastric Ulcer | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrooesophageal Reflux Disease | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Inguinal Hernia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal Ischaemia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatic Disorder | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis Acute | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic Ulcer | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic Ulcer Haemorrhage | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic Ulcer Perforation | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rectal Polyp | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subileus | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Bile Duct Obstruction | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile Duct Stone | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis Acute | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis Chronic | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatic Lesion | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis Allergic | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Foot | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin Necrosis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin Ulcer | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vasculitic Ulcer | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |

| | | | |
|---|------------------|------------------|--|
| Acute Kidney Injury | | | |
| subjects affected / exposed | 7 / 6007 (0.12%) | 8 / 6012 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Kidney Disease | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ketonuria | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephritis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrotic Syndrome | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Failure | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Renal Impairment | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Retention | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 3 / 6007 (0.05%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back Pain | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bursitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Compartment Syndrome | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal Chest Pain | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoarthritis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid Arthritis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertebral Lesion | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal Abscess | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess Limb | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal Abscess | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Cellulitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 5 / 6007 (0.08%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchopulmonary Aspergillosis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |
| subjects affected / exposed | 11 / 6007 (0.18%) | 10 / 6012 (0.17%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium Difficile Colitis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clostridium Difficile Infection | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Diabetic Foot Infection | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Empyema | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocarditis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Endocarditis Bacterial | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endophthalmitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endotoxic Shock | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 4 / 6012 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fungal Oesophagitis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fungal Skin Infection | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Salmonella | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematoma Infection | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Helicobacter Infection | | | |

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|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infection | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious Colitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious Pleural Effusion | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective Exacerbation of Bronchiectasis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective Exacerbation of Chronic Obstructive Airways Disease | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 4 / 6012 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective Spondylitis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injection Site Abscess | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intervertebral Discitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower Respiratory Tract Infection | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Lung Abscess | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Infection | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mediastinitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Parotitis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |

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|---|-------------------|-------------------|--|
| subjects affected / exposed | 58 / 6007 (0.97%) | 48 / 6012 (0.80%) | |
| occurrences causally related to treatment / all | 0 / 59 | 0 / 49 | |
| deaths causally related to treatment / all | 0 / 7 | 0 / 5 | |
| Pneumonia Bacterial | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 4 / 6012 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Pneumonia Pseudomonal | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia Staphylococcal | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative Wound Infection | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Sepsis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Tuberculosis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis Chronic | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Pyoderma | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory Tract Infection | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 4 / 6007 (0.07%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 3 | 0 / 2 | |
| Septic Shock | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 4 / 6012 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 4 | |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft Tissue Infection | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Splenic Abscess | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal Bacteraemia | | | |

| | | | |
|---|-------------------|-------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Staphylococcal Sepsis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic Infection | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Tracheobronchitis | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculous Pleurisy | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 11 / 6007 (0.18%) | 11 / 6012 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Tract Infection Bacterial | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 4 / 6012 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Viral Infection | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound Infection | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound Infection Staphylococcal | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 3 / 6012 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes Mellitus | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes Mellitus Inadequate Control | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Metabolic Decompensation | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failure to Thrive | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fluid Overload | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gout | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 2 / 6012 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperglycaemia | | | |
| subjects affected / exposed | 2 / 6007 (0.03%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoalbuminaemia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |
| subjects affected / exposed | 3 / 6007 (0.05%) | 5 / 6012 (0.08%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypokalaemia | | | |

| | | | |
|---|------------------|------------------|--|
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyponatraemia | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Overweight | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 2 Diabetes Mellitus | | | |
| subjects affected / exposed | 0 / 6007 (0.00%) | 1 / 6012 (0.02%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vitamin B12 Deficiency | | | |
| subjects affected / exposed | 1 / 6007 (0.02%) | 0 / 6012 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events | Rivaroxaban 10 mg or 7.5 mg | Placebo | |
|---|--------------------------------|--------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 250 / 6007 (4.16%) | 280 / 6012 (4.66%) | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 75 / 6007 (1.25%) | 93 / 6012 (1.55%) | |
| occurrences (all) | 81 | 101 | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 114 / 6007 (1.90%) | 147 / 6012 (2.45%) | |
| occurrences (all) | 137 | 174 | |
| Gastrointestinal disorders | | | |

| | | | |
|-----------------------------|-------------------|-------------------|--|
| Diarrhoea | | | |
| subjects affected / exposed | 69 / 6007 (1.15%) | 52 / 6012 (0.86%) | |
| occurrences (all) | 80 | 53 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|--|
| 15 June 2015 | The overall reason for amendment INT-5 was to modify study procedures, clarify eligibility criteria (including the risk score criterion), and to add subject training materials. |
| 19 June 2015 | The overall reason for amendment INT-6 was to clarify prescribed maximum daily dose of thromboprophylactic agents during index hospitalization and to clarify capping of subgroups with certain baseline characteristics or by geographic region or country during enrollment. |
| 31 March 2017 | The overall reason for amendment INT-7 was to increase the maximum number of subjects allowed to be enrolled due to a lower than expected blinded pooled event rate in this event driven study. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported